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| UNIVERSIDAD CENTRAL DEL CARIBE | **Application for Protocol Approval Involving Laboratory Animal Use** | ***UCC/IACUC/Application*** | |
| | | Version# | **# 6** |
| | | Implementation Date | |
| | **Institutional Animal Care and Use Committee** | Last Reviewed/Update | 2023.06.05 |
| | | Approval by IACUC | |

**Table of Contents**

# APPLICATION FOR PROTOCOL APPROVAL INVOLVING LABORATORY ANIMAL USE

= Comments

**Instructions for Filling out this Form**

1. Regulatory agencies require that all applications should be completed and submitted to the Institutional Animal Care and Use Committee (IACUC) to obtain authorization:

   - for all use of vertebrate animals and/or
   - to obtain tissues and cells from vertebrate animals, procured and sacrificed solely and specifically for research and teaching purposes.

2. The National Institutes of Health (NIH) require that funded grant applications, including the use of vertebrate animals, must have an approved IACUC protocol before funds are released to the Principal Investigator (PI) and affiliated institution:
   https://www.niaid.nih.gov/grants-contracts/research-vertebrate-animals
   https://grants.nih.gov/grants/olaw/InvestigatorsNeed2Know.pdf
3. All animal use protocols will require an annual update and must be re-submitted for re-evaluation every three years. Every application will be evaluated as a new document.

4. The electronic version of this application is available at https://www.uccaribe.edu/research10/research-compliance/research-committees/institutional-animal-care-and-use-committee-iacuc/iacuc-forms-and-regulations/ and has to be submitted via e-mail **at least two months** before our scheduled meetings IACUC. IACUC approval needs to be obtained prior to beginning the research project. **Hardcopy applications will not be processed.**

5. Applications submitted by postdoctoral fellows, graduate, and undergraduate students should be accompanied by the name and contact information of his/her academic advisor on the certification section of this application. The advisor must be copied in the email when the IACUC protocol application is submitted.

6. All personnel included in the application are required to have a current animal handling procedure training (less than 3 years).

7. **Protocols involving an animal's exposure to radioisotopes, biological and or hazardous chemical agents and tumor lines/body, and use of rodent breeding must be accompanied with the appropriate attachments (Radioactivity, Biological or Chemical Hazard Committee approval letters).**

**Perdiem for conventional maintenance of laboratory animals are as follows:**

| *Species | **Projects at UCC | **External Projects |
|---|---|---|
| **Rats** | $0.45 | $0.51 |
| **Rats (1-28 days of birth)** | $0.25 | $0.27 |
| **Mice** | $0.35 | $0.38 |
| **Mice (1-28 of birth)** | $0.18 | $0.20 |
| **Caiman** | $1.10 | $1.20 |

*For other species, the perdiem must be evaluated.
**These prices subject to change

# APPLICATION FOR PROTOCOL APPROVAL INVOLVING LABORATORY ANIMAL USE

| FOR OFFICIAL USE | |
|---|---|
| **Universal Number:** | |

 = Comment

| **A. INVESTIGATOR/PERSONNEL INFORMATION** | | | | |
|---|---|---|---|---|
| **Principal Investigator #1** | | | | |
| 1 | Name: (Last name, first name) | | | |
| 2 | Department | ---------- | extension | |
| 3 | E-mail | | | |
| 4 | Emergency Phone | | | |
| **Principal Investigator #2 (if applicable)** | | | | |
| 5 | Name: (Last name, first name) | | | |
| 6 | Department | ---------- | extension | |
| 7 | E-mail | | | |
| 8 | Emergency Phone | | | |

**Research Staff** (List all individuals handling live/dead animals or animal tissue, including PI).

| NAME | ROLE IN THE PROJECT | ANIMAL TRAINING | | | E-MAIL | TELEPHONE NUMBER |
|---|---|---|---|---|---|---|
| | | Date mm/dd/yyyy | General Content | Species | | |
| | Technician | | | ---------- | | |
| | Technician | | | ---------- | | |
| | Technician | | | ---------- | | |
| | Technician | | | ---------- | | |
| | Technician | | | ---------- | | |
| | Technician | | | ---------- | | |

## B. PROJECT INFORMATION

| | | | | |
|---|---|---|---|---|
| 9 | Title of Project | | | |
| 10 | Type of Application (Specify: Research, Training or Pilot (less than six months) | | | |
| Primary | | ---------- | Other (specify): | |
| Additional | | ---------- | | |
| 11 | Protocol Period (mm/dd/yyyy) | From: | To: | |

**IMPORTANT**: The maximum duration of this application is three years, from its approval date

| | |
|---|---|
| 12 | **Study objectives (non-scientific language)**<br><br>Briefly explain the aim of the study and why the study is important to human or animal health, the advancement of knowledge, or the good of society. This statement should not be a reiteration of the objectives of the grant application. |
| | |

## C. CAGING AND HOUSING

| | | |
|---|---|---|
| 13 | Is special caging required to hold animals for more than 12 hours? | ○ Yes ◉ No |
| 14 | Does caging deviate from the standards specified in either the Guide for the Care and Use of Laboratory Animals (GUIDE) or the Animal Welfare Act? | ○ Yes ◉ No |
| 15 | Will special requirements be needed to achieve this protocol (e.g., individual housing, special diets, water or feed restrictions, treatments in feed or water, etc.)? (Provide information) | ○ Yes ◉ No |

**Specifications for Rodents**

| | | |
|---|---|---|
| 16 | Standard caging (microisolator caging is standard in this facility) | ○ Yes ◉ No |
| 17 | Special microisolators are needed since animals are immunocompromised and/or would be exposed to biohazards | ○ Yes ◉ No |
| 18 | Wire bottoms cages are required for this protocol. *(Rat weight should not exceed 500 grams and cannot be housed in this way for more than 9 months)* | ○ Yes ◉ No |
| 19 | Indicate any other special cages that are required in addition to the ones mentioned above. *(Provide justification below)* | ○ Yes ◉ No |

## D. ANIMAL MODEL

**20. Description of Animal to be used:**

Animals must be obtained from Animal Resources Center approved sources/vendors only. Quarantine before entering the UCC Animal House is required for certain animals based on their origin. For more information on animal ordering or arrival, refer to the Handbook for the Use of Laboratory Animals or contact the Animal Resources Center administrative office 787-798-3001, ext. 2096 or betzaida.torres@uccaribe.edu for further information.

| Company/Vendor /Source | Species | Strain | Age | Weight | Sex | Maximum number animals in your project | | | Is an identification method used in addition to a cage card used? If yes, which one? |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | # /week | # /month | # /year | |
| | ---------- | | | | --------- | | | | ---------- |
| | ---------- | | | | --------- | | | | ---------- |
| | ---------- | | | | --------- | | | | ---------- |
| | ---------- | | | | --------- | | | | ---------- |
| | ---------- | | | | --------- | | | | ---------- |

A key principle governing the ethical use of **animals** in research, testing and teaching is that **no animal** life is wasted; the **number of animals** used in each project must be the minimum **necessary** to obtain valid and meaningful results. If rodent breeding is included in the study, Investigators who plan to breed rodents refer to the Mice Breeding Protocol. As part of their study, they must complete the Mice Breeding and Weaning Request Form.

## E. ANIMAL ENRICHMENT INCLUDING BEHAVIORAL EXPERIMENTATION

| | | |
|---|---|---|
| 21 | Does the research require species-specific environmental cage enrichment devices and techniques? | ○ Yes ◉ No |
| 22 | Describe what will be the "animal enrichment device" or which behavioral techniques will be used. | |
| | | |
| 23 | If the answer is yes, specify the area where you will perform the enrichment or behavioral technique. | |
| | | |

## F. USE SITES AND TRANSPORTATION METHODS

| | | |
|---|---|---|
| 24 | Will animals be transported out from the Animal Resources Center? | ○ Yes ◉ No |
| Justification | | |
| Describe the animal transportation route(s), mechanism, and method to cover the animals for transport. | | |
| 25 | Will live animals be returned after handling procedures outside the Animal Resources Center? | ○ Yes ○ No |
| 26 | Will vertebrate animals be housed in these alternate locations for more than 12 hours? | ○ Yes ○ No |
| 27 | Indicate laboratory sites where hazardous tissue (e.g. animal tissues from studies involving radioisotopes, hazardous chemicals, or BSL-2 or higher) will be collected and stored. | |
| | | |

## G. PROCEDURE NARRATIVE

| | |
|---|---|
| 28 | Concisely describe in non-technical language the procedures to which animals will be exposed (in their sequential order) for the duration of the project. **The number of animals detailed here must agree with section D, #20.** The three R's of animal research must be considered (reduction, replacement, and refinement). |

| | Procedure Name | # of animals required | Description of the Procedure |
|---|---|---|---|
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |

| | |
|---|---|
| 29 | Provide flow charts/tables, illustrating experimental design and numbers of animals required for each procedure. **The number of animals detailed here must agree with section D, #20 and section G #27.** |

## H. OFFICE OF LABORATORY ANIMAL WELFARE (OLAW) REQUIRED INFORMATION

If this protocol is duplicated, by **LAW (PUBLIC LAW 99-158 ANIMAL RESEARCH SEC. 495** (https://olaw.nih.gov) you must consider alternatives. In the following section, check which of the following databases and other sources have been searched to assure that the proposed experiments do not unnecessarily duplicate other protocols, that previous experiments do not cause undue distress or pain, and that alternative species or alternative methods have been considered and are not available. The search should include "refining" by using less stressful procedures, "replacing" the species selected, with one lower on the phylogenetic scale, and "reducing" the number of animals you are requesting. The search should have been conducted within the last 3 months.

| | | |
|---|---|---|
| 30 | Does this research duplicate any previous work? | ◯ Yes ◯ No |
| 31 | If the answer is yes, please including the reference | |

What is the scientific justification for the number of animals to be used (i.e. *statistical validity*, previous experience, etc.)?
Please be aware of the following when planning your experiments:

- Limit animal involvement by using the minimum number required to obtain statically valid results.
- Use non-animal methods, such as mathematical models, computer simulation, or in vitro biological systems if possible.
- In addition, include information such as the number of control and experimental groups, number of animals per group or other reasoning.

| | |
|---|---|
| 32 | Justify the rationale for animal use, including why non-animal models cannot be used. |

| | |
|---|---|
| 33 | Justify the selected animal model and why phylogenetically lower species were not selected. |

| | | | |
|---|---|---|---|
| 34 | Approach for sample size determination | ○ | No prior information is available to determine the number of animals required to complete the experiments. (The IACUC accepts requests to perform pilot studies to collect preliminary data to fulfill this purpose, <10 animals **total**) |
| | | ○ | Previous experience by this PI |
| | | ○ | Previous literature |

| | |
|---|---|
| 35 | Write the justification for the total number of animals requested and a description of the power analysis used to determine the sample size. Reference: http://www.nal.usda.gov/awic/newsletters/v7n1/7n1chamo.htm http://statpages.org |

## I. DRUG OR AGENTS ADMINISTRATION

**For <u>all</u> drugs or agents used please note:**

- Animals must be treated <u>exactly</u> as indicated in this protocol with regards to dose and duration of the treatment.
- Changes in type of drug or agent, dose, etc. must be approved via protocol amendment. If a veterinary recommendation results in a permanent change to the protocol, the investigator should submit an amendment to the protocol to obtain IACUC approval.
- Include clinical, laboratory or other parameters used to determine length of treatment.
- Investigators are required to maintain treatment records on all animals. **Refer to: Recommendations for Aseptic Technique, Anesthesia, Analgesia and Post-Operative Care for Rodent Surgery.**
- For anesthesia, analgesia, tranquilizing and paralytic drugs specify dosage in mg/kg (provide justifications below and/or provide information and/or data that demonstrates the proposed dose effectiveness)

| |
|---|
| |

36 **NON-SURGICAL** (excluding anesthetics, analgesics, and tranquilizers).

| Strain | Drug or Agent | Dose | Route | Administration Frequency |
|---|---|---|---|---|
| | | | ---------- | |
| | | | ---------- | |
| | | | ---------- | |
| | | | ---------- | |

37 Duration and Monitoring

Supply duration and method of monitoring treatment efficacy for the drug listed above.

| Drug or Agent | Duration | Drug or Agent Efficacy Monitoring |
|---|---|---|
| | | |
| | | |
| | | |

| 38 | Drugs or agents administered for therapeutic purposes (excluding anesthetics, analgesics, and tranquilizers). |
|---|---|

| Strain | Drug or Agent | Dose | Route | Effect |
|---|---|---|---|---|
| | | | ---------- | |
| | | | ---------- | |
| | | | ---------- | |
| | | | ---------- | |

Describe any adverse effects associated with the administration of these drugs or agents and a detailed plan for monitoring and alleviating these effects if applicable. Identify the person in charge of monitoring the animals after the procedure.

| **If you are using aquatics (e.g., frogs or fish), rats, and mice, please confirm:** | | |
|---|---|---|
| 39 | Will *non-pharmaceutical agents (e.g. anesthetics, analgesics, sedatives, antibiotics, or paralytics) be introduced into rats, mice, birds, or aquatics for veterinary medical care or to relieve pain and distress? | ◯ Yes ◯ No |

**Please note**: As per Universidad Central del Caribe IACUC approved policy, all compounds used in aquatics, rats, or mice for veterinary medical care or to relieve pain and distress (e.g. anesthetics, analgesics, sedatives, antibiotics or paralytics) must be pharmaceutical grade (when available) unless scientifically justified. Cost-savings alone are not considered by the IACUC an adequate justification for using non-pharmaceutical grade drugs for veterinary medical care purposes or relieving pain and distress in these species.

**Non- pharmaceutical agent:* An agent not explicitly prepared to be injected into an animal or human in its purchased form.

Provide a scientific justification for their use and describe methods that will be used to ensure appropriate preparation and administration.

## J. PROCEDURE DETAILS

**Non-Surgical**

**Animal Handling Rationale**

| | | |
|---|---|---|
| 40 | Will blood sampling be conducted? | ◯ Yes ◯ No |

If yes, provide a rationale, method, route, site, volume, and frequency.

| Rationale | Method | Route | Volume (ml) | Frequency |
|---|---|---|---|---|
| | | ---------- | | |
| | | ---------- | | |
| | | ---------- | | |
| | | ---------- | | |

| | | |
|---|---|---|
| 41 | Will food scheduling or restriction (other than standard pre- operative fasting) be conducted?<br>I present evidence that after 12 to 24 hrs. without access, animals efficiently reduce further fluid or energy losses by a combination of behavioral and physiologic adjustments. Reference: Guidelines for Diet Control in Laboratory Animals | ◯ Yes ◯ No |

If yes, provide a rationale, frequency, and duration.

| Rationale | Frequency | Duration |
|---|---|---|
| | | |
| | | |

| | | |
|---|---|---|
| 42 | Will water scheduling or restriction (other than standard pre-operative fasting) be conducted?<br>I present evidence that after 12 to 24 hrs. without access, animals efficiently reduce further fluid or energy losses by a combination of behavioral and physiologic adjustments. Reference: Guidelines for Diet Control in Laboratory Animals | ◯ Yes ◯ No |

If yes, provide a rationale, frequency, and duration.

| Rationale | Frequency | Duration |
|---|---|---|
| | | |
| | | |

| | | |
|---|---|---|
| 43 | Will restraint methods be utilized? (Example: Plastic cone, metabolism cage, manual, etc.) | ◯ Yes ◯ No |

If yes, provide a rationale, frequency, and duration.

| Rationale | Frequency | Duration |
|---|---|---|
| | | |
| | | |
| | | |

| | |
|---|---|
| **44** | **SURGICAL** ***(See: Recommendations for Aseptic Technique, Anesthesia, Analgesia and Post-Operative Care for Rodent Surgery)*** |

| Strain | Drug or Agent | Dose | Route | Administration Frequency |
|---|---|---|---|---|
| | | | ---------- | |
| | | | ---------- | |
| | | | ---------- | |
| | | | ---------- | |

| | |
|---|---|
| **45** | Duration and Monitoring |

Supply duration and method of monitoring treatment efficacy for the drug listed above.

| Drug | Duration | Drug Efficacy Monitoring |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

Describe the post-operative plan to reduce pain. This plan must describe the methods to assess/alleviate pain/distress, recovery criteria, and monitoring criteria. In this plan, identify the person in charge of post-operative care in recovery time.

| | | |
|---|---|---|
| 46 | Will two or more of these survival surgeries involve major procedures (defined as a surgical intervention that penetrates and exposes a body cavity or any procedure that produces substantial or permanent impairment of physical or physiological function?) | ◯ Yes ◯ No |

**Federal guidelines specify that no animals are to be used in more than one major survival operative procedure except in cases of scientific necessity or to provide adequate veterinary care.**

## K. ANIMAL EXPOSURE: These sections will be compared to applicable safety committee (s) regulations and should be consistent between documents.

47 **Radioisotopes:** The Principal Investigator must submit the Use of Radioisotopes Activity in Animal Studies Form for review and approval to the Radiation Safety Committee, after review and approval it must be submitted to the IACUC along with the Application for Protocol Approval Involving Laboratory Use form, prior to the start of the study.

| Will radioisotopes be administered in live animals? | ◯ Yes ◯ No |
|---|---|
| Location of Use: | |

| Strain | Isotope | Activity | Dose | Route |
|---|---|---|---|---|
| | | | | ---------- |
| | | | | ---------- |
| | | | | ---------- |

48 **Biological Hazardous and Introduction of Cell Lines, Transplantable Tumors, Body Fluids, Serum, Tissues and Antibodies into Animals:** The request for the introduction of biological materials such as infectious agents (bacteria, fungi, viruses, parasites, non-human primate materials and recombinant DNA), as well as potential sources of pathogens (human blood, human and murine cell lines, transplantable tumors, body fluids, serum, tissues, and antibodies) into animals must be reviewed and approved by the Institutional Biosafety Committee .

The Principal Investigator must submit the Use of Biological Hazards and Introduction Cell Lines, Transplantable Tumors, Body Fluids, Serum, Tissues, and Antibodies into Animals Form for review and approval to the IBC, and after its review and approval by the IBC it must be submitted to the IACUC along with the Application for Protocol Approval Involving Laboratory Use form, prior to the start of the study.

| Will biological hazards be introduced into the live animal or into the animal tissue? | ◯ Yes ◯ No |
|---|---|

| Strain | Biological Hazards | Dose | Route | Effect |
|---|---|---|---|---|
| | | | ---------- | |
| | | | ---------- | |
| | | | ---------- | |

| Describe any adverse effect associated with the administration of these agents and a detailed plan for monitoring and alleviating these effects if applicable: |
|---|
| |

| Will tumor lines or body fluids be introduced to live animals? | ◯ Yes ◯ No |
|---|---|

| Strain | Agent | Dose | Route | Effect |
|---|---|---|---|---|
| | | | ---------- | |
| | | | ---------- | |
| | | | ---------- | |

| 49 | **Chemical Hazardous Agents** (Do not include drugs used for therapeutic purposes): The Principal Investigator must submit the Use of Hazardous Chemical Agents in Animal Studies Form for review and approval to the Chemical Safety Committee (CSC), after its review and approval by CSC it must be submitted to the IACUC along with the Application for Protocol Approval Involving Laboratory Use form, prior to the start of the study. |
|---|---|

| Will chemical agents be introduced to live animals? | ◯ Yes ◯ No |
|---|---|

| Strain | Chemical Agent | Dose | Route | Effect |
|---|---|---|---|---|
| | | | ---------- | |
| | | | ---------- | |
| | | | ---------- | |

| Describe any adverse effect associated with the administration of these chemicals and a detailed plan for monitoring and alleviating these effects if applicable: |
|---|
| |

| EUTHANASIA | | |
|---|---|---|
| 50 | Will animals be euthanized | ◯ Yes ◯ No |
| 51 | If **YES**, provide details of the euthanasia procedure.<br><br>Indicate the proposed method of euthanasia. If a chemical agent is used, specify the dosage range and route of administration. If the method of euthanasia is not consistent with the AVMA Guidelines for the Euthanasia of Animals, provide scientific justification as to why such method must be used. | |
| See: https://www.avma.org/sites/default/files/2020-01/2020-Euthanasia-Final-1-17-20.pdf for approved euthanasia methods AVMA Guidelines 2020 edition. | | |

## M. LITERATURE SEARCH

**Instructions:**
**Provide at least 2 keywords** and delimiters used to search the literature for references on the background and experimental procedures addressed in this protocol.

| Check | keywords and delimiters | Database | Date Search Performed | Years Covered |
|---|---|---|---|---|
| ☐ | | ---------- | | |
| ☐ | | ---------- | | |
| ☐ | | ---------- | | |
| ☐ | | ---------- | | |
| ☐ | | ---------- | | |
| ☐ | | | | |

## N. PRINCIPAL INVESTIGATOR CERTIFICATION.

**Your electronic signature or e-mail** response on this protocol form certifies your agreement to the following terms.

- I certify the methods described here will be used, and the researcher will amend this protocol as needed when techniques to reduce animal discomfort and pain are identified.
- I certify that my conduct will be in accordance with the PHS Policy, Guide for the Care and Use of Laboratory Animals, DEA regulations, and IACUC Policies. When there is a change in any Animal Regulatory Agency regulation, the IACUC will notify the Principal Investigator so they can request a Protocol Modification to comply with the change if needed.
- I certify the described animal use **does not duplicate previous or existing studies** or is intended to verify previous research.
- I certify this description of the research as provided in this application is complete and accurate.
- I certify I will submit any changes to this description to the IACUC for written IACUC approval prior to implementing any changes.
- I understand non-expired drugs and biomedical supplies will be used.
- I understand that complete animal husbandry and procedural/surgical/testing records will be maintained.
- I understand that if I cannot be contacted, any animal that shows evidence of distress, illness, or pain, will receive emergency care, including euthanasia if necessary, from the veterinary medical staff.
- I understand that the personnel working in this protocol is certified, adequately trained, and experienced. All training courses are valid for three years.
- I ensure that I will inform any recipient (not listed in section A) of any hazard associated with the use of animal body fluids or tissue derived from the studies described in this protocol.
- I certify all activities undertaken as part of this proposal have been fully described in this application. Only activities listed on approved IACUC protocols will be conducted by the investigator, co-investigator, or staff. The research will be suspended at any time the work fails to comply with the Public Health Service, or IACUC policy. The institution is required to report instances of noncompliance to funding agencies and the public health service. These reports become a matter of public record through the agency websites.

**I understand absolutely no research may begin until final IACUC approval is granted.**

| | |
|---|---|
| Today's Date (mm/dd/yy) | |
| Signature: | |

| **O. CHECKLIST** (Please respond in the appropriate box). | | | |
|---|---|---|---|
| **General Sections (required)** | | **Attachments Include** | |
| Investigator/Personnel Information | ☐ | Radioisotopes Use | ☐ |
| Project Information | ☐ | Biological Hazard & Tumor Lines/Body | ☐ |
| Funding Sources | ☐ | Chemical Hazardous Agents | ☐ |
| Animal Model | ☐ | Mice Breeding and Weaning Request Form. | ☐ |
| Caging and Housing | ☐ | | |
| Animal Enrichment | ☐ | | |
| Use Sites and Transportation Methods | ☐ | | |
| Procedure Narrative | ☐ | | |
| Animal Welfare Act Required Information | ☐ | | |
| Drug Administration | ☐ | | |
| Procedure Details | ☐ | | |
| Animal Exposure | ☐ | | |
| Euthanasia | ☐ | | |
| Literature Search | ☐ | | |
| Certification | ☐ | | |

**Application for Protocol Approval Involving Laboratory Animal Use**
**FOR OFFICIAL USE OF IACUC MEMBERS**

**Your determination does not decide the action of this request.**
**This information will be evaluated and presented at the IACUC meeting to decide on its approval.**

| | |
|---|---|
| **Member of IACUC (name):** | |
| **Principal Investigator:** | |
| **# of Protocol:** | |

**ACTION:**

- Approved: ☐
- Approved with suggestions (Please, write the suggestions below): ☐
- More information is required (please, specify what kind of information below): ☐
- Not approved (Please, specify the reasons below) ☐